ISRCTN89085577 https://doi.org/10.1186/ISRCTN89085577

The effect of transfusion on cerebral oxygenation in traumatic brain injury

Submission date	Recruitment status
08/09/2005	No longer recruiting
Registration date	**Overall study status**
06/10/2005	Completed
Last Edited	**Condition category**
03/03/2009	Injury, Occupational Diseases, Poisoning

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
LREC 02/191

Study information

Scientific Title
The effect of transfusion on cerebral oxygenation in traumatic brain injury: a randomised controlled trial

Study objectives
Blood transfusion does not affect brain oxygenation in traumatic brain injury.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Traumatic brain injury

Interventions
Blood transfusion - the patients are randomised to 3 different transfusion triggers

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Brain tissue oxygen partial pressure.

Secondary outcome measures
1. Jugular venous saturation
2. Lactate/pyruvate ratio
3. Neurological outcome
4. Cerebral haemodynamics

Overall study start date
01/07/2002

Completion date
01/12/2005

Eligibility

Key inclusion criteria
1. Greater than 16 years of age
2. Severe traumatic brain injury (i.e. traumatic brain injury resulting in a resuscitated Glasgow coma score of less than or equal to 8, resulting in intracranial hypertension (greater than 20 mmHg for greater than 10 minutes), or requiring neurosurgical intervention
3. Informed assent from the next of kin

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
30

Key exclusion criteria
1. Active haemorrhage
2. Active coronary ischaemia as judged by dynamic electrocardiogram (ECG) changes or positive troponin levels not due to myocardial contusion
3. Inability to place cerebral oxygenation monitors
4. Failure to fall below allocated transfusion threshold during intracranial pressure (ICP) monitoring

Date of first enrolment
01/07/2002

Date of final enrolment
01/12/2005

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Department of Anaesthesia
Cambridge
United Kingdom
CB2 2QQ

Sponsor information

Organisation
Cambridge University Hospitals NHS Foundation Trust (UK)

Sponsor details
Addenbrooke's Hospital
Hills Road
Cambridge
England
United Kingdom
CB2 2QQ
jn254@cam.ac.uk

Sponsor type
Hospital/treatment centre

Website
http://www.cuh.org.uk/

ROR
https://ror.org/04v54gj93

Funder(s)

Funder type
Research organisation

Funder Name
Association of Anaesthetists of Great Britain and Ireland (UK)

Funder Name
Intensive Care Society (UK)

Alternative Name(s)
ICS

Funding Body Type
Private sector organisation

Funding Body Subtype
Associations and societies (private and public)

Location
United Kingdom

Funder Name
Codman (Johnson & Johnson) (UK)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/03/2009		Yes	No